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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,

Plaintiffs,

v.

AMNEAL EU, LTD., AMNEAL PHARMACEUTICALS COMPANY GmbH AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL BIOSCIENCES LLC, and AMNEAL PHARMACEUTICALS PVT. LTD,

Defendants.

Case No. 3:20-cv-18322

[redacted]

CONTAINS CONFIDENTIAL INFORMATION

AMNEAL EU, LTD., AMNEAL PHARMACEUTICALS COMPANY GmbH AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL BIOSCIENCES LLC, AND AMNEAL PHARMACEUTICALS PVT. LTD'S MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

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I. INTRODUCTION

This Court should dismiss Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC's (collectively, "Par") amended complaint because it does not "state a claim to relief that is plausible on its face."[1] Fed. R. Civ. P. 12(b)(6). Par does not allege that Amneal EU, LTD., Amneal Pharmaceuticals Company GmbH, Amneal Pharmaceuticals Of New York, LLC, Amneal Biosciences LLC, and Amneal Pharmaceuticals Pvt. Ltd (collectively, "Amneal") has infringed its patents. Rather, Par only speculates that Amneal might infringe if, first, the FDA allows Par to change its label and if, second, the FDA then requires Amneal to make the same change. This speculated chain of events is insufficient to maintain this action.

Par's infringement claims under § 271(e)(2), based on Amneal's act of filing its Amended New Drug Applications ("ANDAs") cannot stand because a "patented method of using a drug can only be infringed under § 271(e)(2) by filing an ANDA that seeks approval to market the drug for that use." *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012) (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358–59 (Fed. Cir. 2003)). Par asserts two patents directed to treating different types of shock for certain patient populations with specific maximum doses. First, U.S. Patent No. 10,844,435 ("the '435 patent"), which claims a method for treating septic shock patients having one of two specific genotypes (AA or AT) "wherein the maximum dose is 0.085 units/minute." (D.I. 14, Ex. A ('435 Patent), claim 1.) Second, U.S. Patent No. 10,920, 278 ("the '278 patent"), which claims a method for treating

[1] Par is currently maintaining a separate patent infringement action, based on U.S. Patents 9,744,209 and 9,750,785, against Amneal in the District of Delaware, Case No. 1:18-cv-02032. That case is set for trial starting on July 7, 2021. Par has also filed a patent infringement case, based on U.S. Patent 10,844,435 at issue here, against Eagle Pharmaceuticals, Inc., Case No. 3:20-cv-18319 (BRM-DEA). On March 2, 2021, Eagle filed a motion to dismiss. D.I. 8. The arguments presented here mirror those in Eagle's brief. *See* D.I. 9.

post-cardiotomy shock patients having the same specific genotypes "wherein the maximum does is 0.121 units/minute." (D.I. 14, Ex. B ('278 patent), claim 1). But Par does not, and cannot, allege that Amneal is seeking approval for the claimed methods of treatment because neither the claimed patient populations nor the claimed dosing regimens are included in either Par's or Amneal's product labels. Moreover, without any mention of the targeted patient populations or claimed maximum doses in Amneal's labels, Par's § 271(b) claims of induced infringement cannot stand because there is no "explicit direction or instruction by [Amneal] that would lead to active infringement." *Novartis Pharms., Corp. v. Wockhardt USA LLC*, No. 12-cv-3967, 2013 WL 5770539, at *9 (D.N.J. Oct. 23, 2013).

In sum, Par's infringement claims are based on speculation that the FDA will at some point in the future (1) approve the requested change to its label for VASOSTRICT® mentioned in paragraph 42 of the Complaint, and (2) require Amneal to amend its labels in the same way. Par's complaint, therefore, relies on only "prospective labeling amendments . . . rest[ing] on contingent future events that may never occur," and accordingly should be dismissed. *See AstraZeneca*, 669 F.3d at 1381.

II. FACTUAL BACKGROUND

Claim 1 of the asserted '435 patent states:

> A method of increasing blood pressure to a target blood pressure in a human patient with septic shock wherein the patient has an LNPEP AA or AT rs4869317 genotype, the method comprising: intravenously administering to the patient a pharmaceutical formulation comprising vasopressin at a starting dose of 0.01 units/minute and titrating the dose up by 0.005 units/minute at 10 to 15 minute intervals to maintain the target blood pressure, wherein the maximum dose is 0.085 units/minute.

(D.I. 14, Ex. A.) Claim 1 of the asserted '278 patent, set forth below, mirrors claim 1 of the '435 patent except the method is directed to post-cardiotomy shock up to a maximum dose of 0.121 units per minute:

> A method of increasing blood pressure to a target blood pressure in a human patient with post-cardiotomy shock wherein the patient has an LNPEP AA or AT rs4869317 genotype, the method comprising: intravenously administering to the patient a pharmaceutical formulation comprising vasopressin at a starting dose of 0.03 units/minute and titrating the dose up by 0.005 units/minute at 10 to 15 minute intervals to maintain the target blood pressure, wherein the maximum dose is 0.121 units/minute.

(D.I. 14, Ex. B.) The '435 and '278 patents are directed to the administration of vasopressin, an old drug that has been used for decades, to particular patient populations with particular dosage regimens. The claimed methods are not FDA-approved methods of using vasopressin. (*Id*. at ¶ 38, Ex. D at 2.)

Par holds approved New Drug Application ("NDA") No. 204485 for its vasopressin product sold under the brand name VASOSTRICT®. (D.I. 14 ¶¶ 22-23.) Vasopressin "causes contraction of vascular and smooth muscle cells" and is commonly used in an emergency room setting to "increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis)." (*Id*. ¶¶ 23-24.) According to the FDA-approved label for VASOSTRICT®, the maximum dosage of vasopressin for a patient in septic shock is 0.07 units/minute and the maximum dose of vasopressin for a patient with post-cardiotomy shock is 0.1 units per minute. (*Id*., Ex. B at 2.)

Par's current product label for VASOSTRICT® does not include information regarding patients with AA or AT genotypes and does not indicate a maximum dose of 0.085 units/minute. (*See* D.I. 14, Ex. D.) Par alleges that it has sought, but has not yet received, FDA approval for an amendment to include this information in its label. (D.I. 14 at ¶ 42.)

In 2019, the FDA received Amneal's ANDAs 212944 and 212945, seeking authorization to market generic versions of Par's VASOSTRICT® product. Amneal's ANDAs include proposed labeling that would be provided with its proposed ANDA products once approved. Like Par's label for VASOSTRICT®, Amneal's proposed product labels do not include information regarding patients with AA or AT genotypes and do not indicate a maximum dose or 0.085 units/minute. (*See* Declaration of Rebekah Conroy in Support of Defendants' Motion to Dismiss the Amended Complaint ("Conroy Dec."), Exhibits 1 (Proposed label in ANDA No. 212944); Ex. 2 (Proposed label in ANDA No. 212945).)[2] Rather, Amneal seeks approval to market its proposed ANDA products for [redacted].

(Conroy Dec. Ex. 1 at 3, 5; Ex. 2 at 3, 5.)

Par's complaint alleges that it submitted a request to the FDA to amend "the current label for VASOSTRICT®, in order to include new instructions concerning the dosage and administration of VASOSTRICT® … to patients with AA or AT genotypes." (D.I. 14 ¶ 38.) Par's proposed amendment specifies a maximum dose of 0.085 units/minute or 0.121 unit/minute for septic shock and post-cardiotomy shock patients, respectively, with genotypes AA or AT. As Par admits, the FDA has not approved Par's request to amend the current VASOSTRICT® label. (*Id*. ¶ 42.) It is not known whether the FDA will approve the amendment.

[2] Amneal's confidential proposed ANDA labels are "'integral to or explicitly relied upon in the complaint'" and thus "may be considered 'without converting the motion [to dismiss] into one for summary judgment.'" *Borough of Moosic v. Darwin Nat'l Assurance Co.*, 556 F. App'x 92, 95 (3d Cir. 2014) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)). For example, Par makes several allegations relating to Amneal's proposed ANDA labels. (*See, e.g.*, D.I. 14 ¶¶ 62, 68, 78, 84, 94, 100, 110, 116.) Similarly, Par's claim of infringement under 35 U.S.C. § 271(e)(2) necessarily depends on Amneal's confidential proposed ANDA labels. *See AstraZeneca*, 669 F.3d at 1379.

III. LEGAL STANDARDS

To survive a motion to dismiss under FED. R. CIV. P. 12(b)(6), Par's complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Par's "complaint must do more than allege [its] entitlement to relief;" it must "'show' such an entitlement with its facts." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009).

For a patent infringement claim under 35 U.S.C. § 271(e)(2), Par must "show that: 1) the alleged infringer submitted an ANDA; 2) the ANDA was for a drug claimed in a patent or the use of which was claimed in a patent; and 3) the purpose of the ANDA must have been to obtain approval for the commercial manufacture, sale, or use of the drug before the expiration of such patent." *Eisai Co. v. Mutual Pharm. Co.*, No. 06-cv-03613, 2007 WL 4556958, at *9 (D.N.J. Dec. 20, 2007). "[T]he burden is on [Par] to prove that each and every limitation of the patent as construed is found in the accused [ANDA]." *Organon, Inc. v. Teva Pharm., Inc.*, 244 F. Supp. 2d 370, 377 (D.N.J. 2002) (citing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1565 (Fed. Cir. 1997)).

Par's claims for relief under 35 U.S.C. § 271(b) requests that the Court grant declaratory judgment that Amneal will induce infringement of the '435 and '278 patents. (*See* D.I. 14 ¶ 68, 84, 100, 116.) "The availability of declaratory relief is limited [] by Article III of the Constitution, which restricts judicial power to the adjudication of 'Cases" or "Controversies.'" *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 879 (Fed. Cir. 2008). In a motion to dismiss for lack of subject matter jurisdiction under FED. R. CIV. P. 12(b)(1), "[t]he burden is on [Par] to prove that subject matter [jurisdiction] exists." *Novo Nordisk Inc. v. Mylan Pharm. Inc.*, No. 09-cv-02445, 2010 WL 1372437, at *5 (D.N.J. Mar. 31, 2010). Par must show that the facts alleged

support a finding that there is a "substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1345 (Fed. Cir. 2010) (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)).

To satisfy the "immediacy and reality" prong of the inquiry, Par must show "(1) an injury-in-fact, *i.e.*, a harm that is 'concrete' and actual or imminent, not 'conjectural' or 'hypothetical,' (2) that is 'fairly traceable' to the defendant's conduct, and (3) redressable by a favorable decision." *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008). Moreover, "no presumption of truthfulness attaches to the allegations in [Par's] complaint." *Hoffman-La Roche, Inc. v. Genpharm Inc.*, 50 F. Supp. 2d 367, 372 (D.N.J. 1999) (citing *Mortensen v. First Fed. Savings & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977)).

IV. ARGUMENT

A. Par's Claims Under 35 U.S.C. § 271(e)(2) Must Be Dismissed Because Par Fails to State A Claim Upon Which Relief May Be Granted

1. As Par Admits, the Accused Amneal ANDAs Do Not Seek Approval for the Methods Claimed in the '435 and '278 Patents

The Court should dismiss Par's § 271(e)(2) claims because Par does not, and cannot, allege facts supporting a claim that Amneal seeks approval to market its vasopressin products for the use specified in the '435 and '278 patents. To infringe a method claim under § 271(e)(2), the accused infringer must be seeking FDA approval to market a drug for a use claimed in a patent. *Warner-Lambert*, 316 F.3d at 1354–55 & 1358–62; *see also AstraZeneca*, 669 F.3d at 1379 ("[A] patented method of using a drug ***can only be infringed under § 271(e)(2)*** by filing an ANDA that seeks approval to market the drug for that use." (emphasis added)) (citing *Warner-Lambert*, 316 F.3d at 1358–59). In *Warner-Lambert*, the plaintiff marketed a drug with one indication, and the generic manufacturer filed an ANDA "seeking approval to market a generic

formulation … only for the same indication" as the plaintiff. 316 F.3d at 1352. The plaintiff, however, sued the generic manufacturer for infringement of a patent claiming different methods of use than those approved by the FDA. *Id.* Affirming the district court's grant of summary judgment, the Federal Circuit explained that the plaintiff did "not have a cause of action under § 271(e)(2)(A)" because the generic manufacturer did not "submit[] an application to sell a drug the use of which is claimed in an extant patent." *Id*. at 1362.

The circumstances here mimic those in *Warner-Lambert* and compel dismissal. The '435 patent claims a method of "administering … vasopressin … wherein the maximum dose is ***0.085 units/minute***" for "a human patient with septic shock … [and an] AA or AT … genotype." (D.I. 14, Ex. A at claim 1 (emphasis added).) The '278 patent claims a similar method of administering vasopressin except the maximum dose is ***0.121 units/minute*** and the target patient population is patients with post-cardiotomy shock and an AA or AT genotype. (D.I. 14, Ex. B at claim 1.) To maintain a claim of infringement, Par must plead sufficient facts that "the accused [ANDA] contains each limitation of the asserted claim(s)." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). But Amneal's ANDAs request approval for a lower maximum dosage ([redacted]) than claimed in the '435 or '278 patents. (Conroy Dec. Ex. 1 at 3, 5; Ex. 2 at 3, 5 (emphasis added).) Likewise, Amneal's ANDAs make no mention of treating specific patients with "an LNPEP AA or AT rs4869317 genotype." (D.I. 14, Ex. A, claim 1; Conroy Dec. Exs. 1 and 2.) Indeed, by admitting that Amneal will have to "amend the proposed labeling" (D.I. 14, ¶¶ 47-48), Par seemingly acknowledges that the current proposed labels in Amneal's ANDAs do not infringe the claimed methods.

Thus, setting aside Par's speculation, Par has not sufficiently alleged that Amneal's ANDAs infringe the '435 or '278 patents because the instructed use of Amneal's ANDA products "falls outside the . . . claims of the ['435 and '278 patents]." *Par Pharm.*, 2017 WL 452003, *6.

2. Par's Claims Based On A Future Label Are Not Ripe

Par's argument that Amneal's ANDA products will infringe in the future if Amneal is required to amend its labels is not ripe and cannot save Par's § 271(e)(2) claims. A claim is unripe "if it rests upon ***contingent future events*** that ***may not occur as anticipated***, or indeed ***may not occur at all***." *Texas v. United States*, 523 U.S. 296, 300 (1998) (emphasis added, internal quotations omitted). Section 271(e)(2) claims "based on presumed future labeling amendments are unripe" and should be dismissed. *AstraZeneca Pharm., LP v. Apotex Corp.*, 669 F.3d 1370, 1381 (Fed. Cir. 2012). In *AstraZeneca*, the generic manufacturer did not seek approval for the "patented indications." *Id*. at 1374. Like Par, the patentee there "alleged that the FDA will require [the accused generic manufacturers] to amend their ANDAs at some unspecified point in the future to include all FDA-approved indications for [the drug], including those covered by the ... patents, resulting in infringement under § 271(e)(2)." *Id*. at 1380. The Federal Circuit rejected this argument as speculative and affirmed dismissal.

Par itself has previously attempted this same argument in this Court, unsuccessfully, in *Par Pharm., Inc. v. Luitpold Pharm., Inc.*, 2017 WL 452003. There, the accused ANDA product "d[id] not infringe Par's patents," *id.* at *5, but Par contended then, as it does now, that the defendant "will have to amend its ANDA in order to obtain FDA approval," and that this amendment would result in infringement. *Id*. at *4, *6 (internal quotations omitted). The Court rejected Par's argument: "Because Par's claim is entirely premised on speculation that future, uncertain amendments to [the generic manufacturer's] ANDA will infringe Par's patents, and

there is no question that the drug specified in [the generic manufacturer's] ANDA does not infringe the Patents-in-Suit, judgment in favor of [the generic manufacturer] is warranted." *Id*. at *6.

The same reasoning requires dismissal here. Amneal indisputably does not "seek[] approval for activities that would constitute infringement" of the '435 or '278 patents. *AstraZeneca*, 669 F.3d at 1381. Par's argument that the FDA will require Amneal "to amend the proposed labeling for its Proposed ANDA Products" is speculative, as it was in *AstraZeneca*. (D.I. 14 ¶ 47.) Therefore, like *AstraZeneca*, "nothing in the record indicates that the FDA [will] require[] [Amneal] to add further indications" or instructions to its label. 669 F.3d at 1381. In fact, the future amendments in this case is even more speculative than in *AstraZeneca*. Here, the FDA has not even approved Par's requested label change, let alone asked Amneal to amend its labels.

3. Par's Inducement Claims Under § 271(e)(2) Are Not Legally Cognizable

Par's attempts to argue inducement based on § 271(e)(2) infringement, (D.I. 14 ¶ 62, 78, 94, 110), fare no better. Par alleges that, regardless of whether the FDA requires Amneal to amend its ANDA labeling, Amneal would still infringe the '435 and '278 patents because, "if Amneal were to obtain FDA approval to market and sell its Proposed ANDA Products, it would market and sell it to hospitals and/or group purchasing organizations and other distributors … as a generic substitute for VASOSTRICT® to be used and administered in the same manner as VASOSTRICT®." (D.I. 14 ¶ 49.) In other words, Par speculates that, first, the FDA grants Par's requested labeling change, and, second, physicians would then use Amneal's vasopressin products for a use not specified in Amneal's labels (i.e., off-label).

But Par cannot make a claim for induced infringement under § 271(e)(2) based on speculative off-label use. *See AstraZeneca*, 669 F.3d at 1381. As the Federal Circuit has made clear, this argument "is not cognizable under [35 U.S.C. §] 271(e)(2)." *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1324 (Fed. Cir. 2003). Indeed, Par "is precluded from suing [Amneal] under section 271(e)(2) for inducing infringement of the [patents in suit], because [Amneal is] not seeking FDA approval for the uses claimed in the patents and because the uses claimed in the patents are not FDA-approved." *Id.* at 1334. "Because the product[s] that can be manufactured under [Amneal's] ANDA[s] do[] not infringe Par's patents, [Amneal's] motion [to dismiss should be] granted." *Par*, 2017 WL 452003, at *5.

B. Par's Claims Under 35 U.S.C. § 271(b) Must Also Be Dismissed Because This Court Lacks Subject Matter Jurisdiction and Par Fails to State A Claim Upon Which Relief May Be Granted

1. This Court Lacks Subject Matter Jurisdiction Over Par's Claims For Relief Under § 271(b)

The Court should dismiss Par's claims under § 271(b) because there is no subject matter jurisdiction. Par is "seeking to establish declaratory judgment jurisdiction[, so it] bears the burden of demonstrating that an Article III case or controversy exists at the time the claim for declaratory relief is filed." *Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1328 (Fed. Cir. 2012). To present an actual case or controversy, Par must show that "'the facts alleged, under all the circumstances, show that there is a substantial controversy … of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014). Par fails to do so here.

Par cannot meet its burden to establish either "reality" or "immediacy." Par's complaint contains no allegations that Amneal is ***currently*** "actively induc[ing] infringement," but only that it "might some day." *IGI Labs., Inc. v. Mallinckrodt LLC*, No. 13-cv-02044, 2014 WL 1652790,

at *1 (D. Del. Apr. 22, 2014). As discussed above, Par's claims depend on multiple layers of speculation. Par speculates that the FDA will approve Par's request to amend the VASOSTRICT® label "to include new instructions concerning the dosage and administration of VASOSTRICT® … to patients with AA or AT genotypes." (D.I. 14 ¶ 34.) Par then speculates that Amneal ***may*** be required to "amend the proposed labeling for its Proposed ANDA Product" to "include … the same instructions for treating patients with the AA or AT genotypes" in order to obtain FDA approval. (*Id.* ¶¶ 43-44.) But as noted, it is unclear whether the FDA will approve Par's amendment, and even if so, it is unclear whether the FDA would require Amneal to amend its proposed labels. Par additionally speculates that if Amneal's product is not "AB" rated, Amneal would need to affirmatively market its product (*id.* ¶ 50), but Par does not allege that Amneal is currently doing so or that Amneal has any plans to do so in the future.

Thus, Par's claim, which, at best, alleges "fluid and indeterminate" circumstances regarding the accused product, "fails to meet constitutionally-mandated reality requirements." *Matthews*, 695 F.3d at 1330 (citing *Cat Tech*, 528 F.3d at 882). "The greater the variability of the subject of a declaratory-judgment suit, particularly as to its potentially infringing features, the greater the chance that the court's judgment will be purely advisory, detached from the eventual, actual content of that subject—in short, detached from eventual reality." *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004). "Simply put, because [the FDA's ultimate determinations on Par's and Amneal's respective applications] are unknown, any judicial determination as to whether [Amneal's generic vasopressin] could infringe [the patents in suit] would constitute an advisory opinion based upon a hypothetical set of facts." *Matthews*, 695 F.3d at 1331 (citing *Arctic Corner, Inc. v. U.S.*, 845 F.2d 999, 1000 (Fed. Cir. 1988)).

Likewise, Par's speculative allegations fail the "immediacy" requirement. Par's claims "lack[] immediacy because there is no evidence as to when, if ever, [Amneal's generic vasopressin] will be used in a manner that could potentially infringe" the '435 or '278 patents. *Id.* at 1328. Moreover, Par pleads no facts supporting the conclusion the events about which it speculates will occur any time in the near future and "the greater the length of time before potentially infringing activity is expected to occur, the more likely the case lacks the requisite immediacy." *Id.* at 1330 (*citing Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 881 (Fed. Cir. 2008)).

Because Par's § 271(b) declaratory judgment claims "lack[] the requisite immediacy and reality to support the exercise of declaratory judgment jurisdiction," they should be dismissed for lack of subject matter jurisdiction. *Id*. at 1328.

2. Par's § 271(b) Claims Must Be Dismissed Because Par Fails to State a Claim Upon Which Relief May Be Granted

Even if the Court has jurisdiction, it should dismiss Par's § 271(b) claims. To survive a motion to dismiss, Par has to plead facts that could establish "that [Amneal's] actions induced infringing acts and that [Amneal] knew or should have known [its] actions would induce actual infringement." *Warner-Lambert*, 316 F.3d at 1363 (citing *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 533 (Fed. Cir. 1990)) (internal quotations omitted). Par can prove neither. Par does not even allege that Amneal has asked the FDA for a label that would permit infringement. *See Novartis*, 2013 WL 5770539, at *8. "Section 271(b) imposes liability on those who 'actively induce[] infringement,' not on those who might some day induce infringement." *IGI*, 2014 WL 1652790, at *1 (alteration in original). The FDA may approve Amneal's ANDAs without Par's proposed instructions included. Consequently, Par's claim is not ripe because the

"contingent future events" Par hinges its claim on "may not occur as anticipated, or indeed may not occur at all." *Texas*, 523 U.S. at 300.

Further, even if Par's requested amendment were already approved (which it is not), Par's inducement claim would still need to be dismissed because a key element of inducement is "actual intent to cause the acts which constitute the infringement." *Novartis*, 2013 WL 5770539, at *9 (citing *Hewlett-Packard*, 909 F.2d at 1469). But Par's Complaint does not "identify any explicit direction or instruction by [Amneal] that would lead to active infringement under § 271(b)." *Novartis*, 2013 WL 5770539, at *9. Indeed, courts have found no intent where, like Par's claim, the "ANDAs seek approval only for [a non-infringing use] and [its] proposed labels do not mention [the claimed use]." *Id*. The "mere knowledge of possible infringement by others does not amount to inducement." *Warner-Lambert*, 316 F.3d at 1364. Par's allegation of a mere possibility that some day in the future the FDA may require Amneal to amend its proposed labels is not sufficient to establish that Amneal knows now that its ANDAs will induce infringement. Par's further speculation that Amneal may engage in marketing its product, and may "make affirmative representations to its customers that Amneal's Product[s are] equivalent to VASOSTRICT®" is similarly insufficient to show an affirmative step to induce infringement of the asserted patents.

For the reasons discussed above, allegations dependent on speculative and uncertain future events simply cannot establish a ripe case and controversy, and Par's § 271(b) claims should be dismissed. *See AstraZeneca*, 669 F.3d at 1381.

V. CONCLUSION

For the reasons set forth above, Par's Complaint against Amneal should be dismissed.

Respectfully submitted,

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